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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,620	10/25/2001	Abraham Scaria	5046US	2242

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,620	SCARIA ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim 7 is pending.

The brief description of drawings is objected because while the description of the drawings refers to "Figure 4" or "Figure 6", the drawings only depict Figures 4A, 4B, 6A, and 6B. A change from "Figure 4 illustrates" to – Figures 4A-4B illustrate --, for example, would obviate the objection. Appropriate correction is required.

The specification is also objected because this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because numerous pages from the specification recite a polypeptide sequence without reciting a sequence identifier. While a paper copy of the sequence listing together with the computer readable file have been entered, the polypeptide sequence as disclosed in the specification must contain a reference to SEQ identifier. Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention can be reasonably construed as a method of promoting blood coagulation in an individual having a blood coagulation defect and in need thereof, wherein a genus of Factor VII polypeptide coding gene is embraced to practice the full breadth of the claimed invention.

The specification and prior art of record only discloses the availability of a human factor VII gene. Such description does not appear to represent a genus of a Factor VII gene. The lack of a sufficient description of the specific structures of a representative number of species of factor VII genes, would not support applicant's possession of a generic gene therapy method, wherein a generic factor VII gene is employed. In other words, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims, requires more than a mere statement that it is part of the invention and a reference of just one disclosed species; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of polynucleotide sequences coding for a factor VII. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming a generic method, wherein a necessary requirement a generic factor VII gene is essential for the practice of the claimed invention, without defining what means will do so is not in compliance with the written description requirement. Rather, it is an

attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). Even a mere disclosure of a probing strategy or plan for the identification and isolation of factor VII genes, which are yet to be discovered and available in the prior art without the complete nucleotide sequence of the sequences, which are deemed essential to the practice of the full breadth of the claimed invention, is not sufficient to demonstrate that Applicants were in possession of the claimed invention as recited in claims 19 and 23. Thus, it is not apparent to one skilled in the art as to how claims encompassing the use of a genus of factor VII genes, find an adequate support from this instant disclosure at the time the invention was made.

In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for:

A method of promoting blood coagulation in an individual having a blood

coagulation defect and in need thereof, comprising administering to the individual a blood coagulation enhancing effective amount of a DNA vector encoding a human Factor VII polypeptide that can be converted to Factor VIIa when expressed in said individual, said Factor VII polypeptide comprising an enzymatic cleavage site susceptible to cleavage by furin, wherein said enzymatic cleavage site is located in the area of about amino acid 147 through about 154 of said human Factor VII, whereby said cleavage by furin produces Factor VII heavy chain and Factor VII light chain molecules.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Since the claimed invention is not supported by a sufficient written description (for possessing of the genus of polynucleotide sequences coding for Factor VII genes), which is essential to the practice of the claimed invention, particularly in view of the reasons set forth above, one skilled in the art would not known how to use and make the claimed invention as broadly claimed so that it would operate as intended.

In addition to the above lack of written description, the specification and the prior art of record (High *et al*) only provides sufficient guidance and teachings for a skilled artisan to modify a human Factor VII by constructing an enzymatic cleavage site at the area of about amino acid 147 through about 154 of said human Factor VII, see pages 6, 8 and 9 from the specification. A review of the as-filed specification shows that "activation of FVII to FVIIa involves proteolytic cleavage at a single peptide bond between Arg-152 and Ile-153, resulting in a two-chain molecule consisting of a light

chain of 152 amino acid residues and a heavy chain of 254 amino acid residues held together by a single disulfide bond". Thus, in order for such Factor VII to be produced, wherein a two-chain molecule consisting of a light chain of 152 amino acid residues and a heavy chain of 254 amino acid residues held together by a single disulfide bond is generated, an enzymatic cleavage site susceptible to cleavage by furin must be modified or constructed in the area of about amino acid 147 through about 154 of a human Factor VII. Thus, it is not apparent how a skilled artisan, without any undue experimentation, could reasonably extrapolates from the teaching and guidance of the specification and prior art to the full breadth of the claim, which embraces an incorporation of an enzymatic cleavage site susceptible to cleavage by furin at any site within a human factor VII.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 7 is rejected under 35 USC 102(e) as being anticipated by High *et al.* (WO 01/70763 A1, which claims priority to provisional application 60.191,331, filed March 2000, a copy of which is enclosed herein).

The claim embraces a method of promoting blood coagulation in an individual having a blood coagulation defect and in need thereof, comprising administering to the individual a blood coagulation enhancing effective amount of a DNA vector encoding a human Factor VII polypeptide that can be converted to Factor VIIa when expressed in said individual, said Factor VII polypeptide comprising an enzymatic cleavage site susceptible to cleavage by furin, wherein said enzymatic cleavage site is located in the area of about amino acid 147 through about 154 of said human Factor VII, whereby said cleavage by furin produces Factor VII heavy chain and Factor VII light chain molecules.

High teaches the same throughout the disclosure, abstract, page 4, last paragraph bridging page 5, page 5, third full par., and lines 24-28, page 6, lines 19-31, page 7, lines 10-20, Figures 4 and 5., page 10 bridging page 11, and pages 28-40. The abstract, and pages 3-6 of the provisional application has sufficient written support for the claimed invention and pages cited from the WO publication.

Thus, High et al anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0184.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

DAVE T. NGUYEN
PRIMARY EXAMINER

Dave Nguyen
Primary Examiner
Art Unit: 1632